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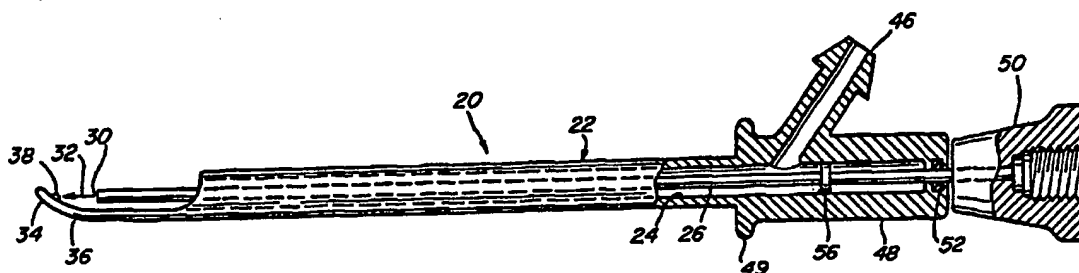
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(54) Title: INSTRUMENT HAVING A SELECTIVELY SHAPEABLE TIP FOR CREATING A FLUID JET



(57) Abstract

This invention is an instrument (20) for delivering a variable pressure stream of fluid (32) as a coherent jet. The instrument may be configured for holding in the hand of the user or for manipulation by machine control. The jet orifice (30) may be oriented axially, transversely or obliquely. A deflector (36) may be slidable or pivotable to ensure a small instrument profile. The instrument may be moldable allowing the user to reshape the jet tip into a desired configuration. The instrument may be remotely steerable and enable the user to selectively alter the direction of the jet without having to remove the instrument from the surgical site.

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**INSTRUMENT HAVING A SELECTIVELY SHAPEABLE TIP
FOR CREATING A FLUID JET**

FIELD OF THE INVENTION

5 The invention relates to an instrument for creating a fluid jet.

BACKGROUND OF THE INVENTION

Systems are known which employ a nozzle or handpiece having a small diameter orifice to generate a jet stream as a high pressure fluid flows therethrough. Instruments specifically for use in surgical applications also have been proposed. U.S. Patent No. 3,930,505 discloses a variable pressure jet for disintegrating eye lens tissue. A system for use in hepato-biliary surgery, known as the Hepatom, has been reported in the literature and may be available outside the United States. U.S. Patent No. 5,370,609, and related European patent applications 0 485 133 and 0 489 496, describe a water jet catheter which delivers a high pressure liquid stream to dislodge, emulsify and remove deposits from a vein or artery.

SUMMARY OF THE INVENTION

The present invention is an instrument for delivering a variable pressure stream of fluid as a coherent jet. The instrument may be configured for holding in the hand of a user or for manipulation by machine control, such as an X/Y/Z positioner. The instrument includes an elongated body having a lumen communicable with a source of pressurized fluid that terminates in one or more fine axial or transverse jet orifice(s) having a diameter in the range of tenths of millimeters, preferably 0.1 millimeter. The jet orifices may be oriented axially, transversely or obliquely. A hair-thin cutting beam is formed as the fluid stream spews through the tiny jet orifice at pressures as high as 50,000 p.s.i. For the purposes of this application, the term "fluid jet cutting" is intended to broadly include the use of a high pressure fluid stream to cut, drill, bore, perforate, strip, delaminate, liquefy, ablate, shape and other forming and machining operations. A hand tightenable connector may be provided at a proximal end of the instrument to ensure a leaktight seal with a delivery tube that conducts the fluid under pressure into the instrument.

30 Various configurations of the jet creating instrument tip may be employed. Preferably, the tip is selectively moldable allowing the user to reshape or bend the jet tip into a configuration, or at an angle, which facilitates positioning at the cutting site. This feature is especially attractive where the locus of cutting is difficult to reach. A deflector or catcher may

be provided opposite the orifice to transform the liquid jet into a harmless spray, preventing the fluid arc from cutting deeper than is desired or from attacking surrounding areas if the stream becomes misdirected. To ensure a small instrument profile, the catcher may be slidable (in the axial mode) or pivotable (in the transverse mode) from a slender configuration employed during
5 insertion of the instrument to an expanded configuration at the cutting site. Alternatively, one or more jets may be oriented to create a deflecting spray that accomplishes the same aim as the catcher. A separate outlet may be provided on the jet forming instrument which is communicable at a proximal end with a source of suction to allow aspiration of debris caused by the fluid cutting and the cutting medium. Alternatively, a separate suction line may be
10 employed.

The jet instrument is particularly suitable for use in surgical procedures. Selective variation of the jet stream pressure, between 1 and 50,000 p.s.i., allows the surgeon to cut hard bone, soft bone, cartilage and tissue, to strip away tissue exposing underlying organs or vessels or, simply, to wash away blood and debris created by the surgical procedure. The latter irrigating
15 function ensures good visibility of the operative site. Preferably, the jet is a fine, coherent stream of sterile cutting solution, such as physiological saline or, perhaps, a liquefied gas such as carbon dioxide, which cuts or ablates the tissue or bone, and the stream may then be used to pulverize the biological fragments into smaller pieces. The emulsified debris may be flushed or evacuated from the surgical site. The jet wand may include a suction nozzle or a separate suction line may
20 be employed. Alternatively, positive pressure evacuation may be employed to remove the effluent.

Selective variation of the jet pressure allows the surgeon to target precisely a visible low pressure stream on the portion of the bone or tissue to be excised and then to cut the bone or tissue with the already pin-pointed jet simply by increasing the jet to a higher, cutting pressure.
25 A physiologically inert dye may be dispersed in the sterile cutting fluid to enhance focusing of the low pressure stream. Even when fully submersed in fluid, the jet is ascertainable by the cavitation within the surrounding solution. The hair-thin fluid beam, having a diameter in the tenths of millimeters and, preferably, in the range from 20-500 microns, permits the surgeon to make fine controlled incisions without damaging neighboring tissue, organs, vessels or nerves.

30 A slender, hand-holdable wand or nozzle is preferred for surgical applications, facilitating use of the fluid jet cutting system in procedures which present narrow spaces and complicated geometries. The reduced configuration suggests use of the instrument in arthroscopy and other

procedures where small openings and cannulas may be used to enter the operative field. Alternatively, the jet forming instrument may embody a tip at the distal end of a burst resistant catheter, such as is disclosed in U.S. Patent No. 5,370,609, the contents of which are incorporated herein by reference.

5 It is an object of the present invention to provide a jet creating instrument with a controlled length cutting beam.

 It is an additional object of the present invention to provide a jet forming instrument with a slender profile.

 It is a still further object of the present invention to provide a jet instrument with a tip that
10 is remotely manipulable.

 Other objects and features of the advantages of the present invention will become apparent from the following detailed description when taken in connection with the accompanying drawings which disclose multiple embodiments of the invention. It is to be understood that the drawings are designed for the purpose of illustration only and are not
15 intended as a definition of the limits of the invention.

DESCRIPTION OF THE DRAWINGS

 The forgoing and other objects and advantages of the invention will be appreciated more fully from the following drawings in which:

20 Figs. 1 and 2 illustrate a jet wand with an axially moveable delivery tube for varying the length of the fluid jet;

 Figs. 3 and 4 show a jet wand with a displaceable transverse jet;

 Fig. 5 illustrates a stabilizing mechanism for preventing rotation of the delivery line in the wand shown in Fig. 4 as seen from line 5-5;

25 Figs. 6 and 7 illustrate a transverse jet wand with a pivoting deflector;

 Fig. 8 shows a pistol grip and trigger portion of a jet wand;

 Figs. 9 and 10 show a jet wand having a formable portion; and

 Figs. 11, 12 and 13 illustrate an instrument for creating a fluid jet having a steerable tip.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

A jet instrument 20, illustrated in Figs. 1 and 2, includes an elongated body 22 having a central lumen 24 and a displaceable fluid delivery line 26 extending therethrough. The delivery line is constructed of burst resistant hypotube, such as 14XT gauge type 304 or 316 stainless steel, which is rated for pressures in excess of 50,000 p.s.i. An axially facing jet at the distal tip 30 of the delivery line creates a fine beam of high pressure fluid 32. A distal tip 34 of a catcher or deflector 36 curves upwardly from the elongated body into the path of the fluid jet, diffusing the liquid beam into a harmless spray. The deflector may include a wear resistant surface, such as the illustrated ball bearing 38, to increase the working life of the instrument. Modification of the instrument to form an electro-cautery device is contemplated. The deflector may have a sharpened edge and tip 40, 42, respectively, allowing the surgeon to create an incision with the instrument. Also, a pointed tip may be employed to pierce and hold an article while it is being cut.

A side port 46 extends from the main body and may be placed in communication with a source of suction to draw debris and effluent away from the surgical site. Alternatively, the port may be connected to a source of medication or irrigation. It also is contemplated to provide additional side ports if required by a specific application.

Retracting a handle 50 draws the jet away from the catcher, allowing the user to selectively vary the size of the cutting beam. Where the bone, cartilage or tissue being removed is large, the jet will be more proximally disposed to increase the length of the liquid arc. A distal positioning may be appropriate where a small target is presented. A seal 52 is provided in the proximal end of the body, around the hypotube, preventing leakage of the fluid yet permitting axial movement of the delivery line. A limit washer 56, secured to the delivery tube, is halted by a stop in the proximal end of the body, preventing further retraction of the delivery tube. The washer may be positioned to prevent the jet opening from being withdrawn into the body lumen, if desired. The handle, a contoured surface of the instrument body 48 including an annular rim 49 facilitate relative movement of the delivery tube and body by a user.

An instrument with a transverse jet is illustrated in Figs. 3-5. The tip of the delivery tube is pre-shaped with an outward curve 60, allowing the user to selectively vary the length of the cutting beam by incrementally retracting the delivery tube into the body lumen. A fully retracted delivery tube, as shown in Fig. 4, provides a reduced profile compatible with placement of the instrument, particularly through narrow passages. The distal tip, preferably, is resilient.

assuming a straight configuration when seated in the body lumen but springing back to an outwardly curved shape upon deployment. A portion 64 of the distal segment of the main body is exposed, permitting expansion of the jet tip. The deflector is provided on an axial extending face 66 opposite of the transverse jet. To prevent rotation of the delivery line, an alignment washer 68 having a groove 72 is mated with a positioning rail 74 in the body. The groove and rail arrangement permits axial movement of the delivery line but prevents rotation which could, detrimentally, lead to a misdirected spray beyond the protection of the deflector.

An instrument 90 with a pivoting deflector 92 is illustrated in FIGS. 6 and 7. A deflector is mounted on the distal end of the delivery tube by pins 94 (only one pin is shown). The ends of the deflector are angled outward with respect to the delivery tube such that the deflector can rock on the pins. When in a retracted position, shown in Fig. 7, an elastomeric sheath 96 disposed at the distal end of the body, surrounds the deflector and maintains the deflector in a reduced profile. Extension of the deflector out of the sheath beyond the pins causes the deflector to pivot into the open configuration, shown in Fig. 6. When in this configuration, the deflector is able to diffuse a transverse jet stream.

Fig. 8 shows the proximal end of a jet wand configured with a pistol grip 130 for easy manipulation by a user. The jet handle may be provided with a trigger 132 which is connectable to a control 134 for varying the pressure of the fluid jet.

Figs 9 and 10 illustrate a jet wand having a moldable tip which facilitates navigation of the instrument around obstructions during positioning of the jet relative to the surgical site. Consequently, a moldable wand has a particular advantage over conventional percutaneous cutting probes, such as burrs and rotary cutters or shavers, which require a drive shaft for rotary motion which is generally incapable of bending without leading to mechanical failure. Because the cutting energy of the fluid jet wand is a pressurized liquid, bends and turns in the delivery line will not detrimentally impede the generation of a cutting force at the distal tip.

The preferred material for forming the delivery tube and body is a thick wall gauged stainless steel which is shapeable without kinking or occluding the high pressure fluid lumen. The components are preferably formed from a malleable alloy or are subject to heat treatment to achieve the requisite kink resistance and flexibility. Fig. 9 shows a delivery tube 120 having a bend 122 at the distal and which can be adapted to direct the jet spray 124 out of line-of-sight. The tip of the instrument may be provided with a greater degree of hardness than a more proximal section, permitting the distal tip to maintain an edge where desired as well as to allow

the instrument end to be used as a manipulator of tissue and bone during a procedure.

Fig 10 illustrates a different arrangement for selectively molding the jet tip. Here, a relatively thick, semi-rigid tube 142 is surrounded by a relatively thin walled flexible metal sheath 144. The tube 142, preferably constructed of a polymeric material, such as nylon, has a lumen 146 adapted to carry the pressurized fluid to the jet opening 148 at the distal end of the wand. The flexible steel imparts moldability to the device.

A remotely steerable jet wand is illustrated in Figs. 11-13, allowing a user to selectively alter the direction of the jet without having to remove the instrument from the surgical site. This instrument is particularly indicated for use where the surgical site is remotely visualized. A main body 180 has a delivery tube 181 extending therethrough. A flexible delivery tube distal tip 182 is fixed at diametrically opposed sides by ends of high tensile wires 184, 186. The control wires extend along the length of the main body, preferably through a pair of parallel lumens 192, 194, shown in Fig. 12. Manipulation of the proximal ends of the wires causes the distal tip to bend accordingly. Selective, real time shaping of the distal tip should facilitate travel of the surgical wand to the cutting site and will allow the surgeon to vary the direction of the fluid cutting jet. Fig. 13 illustrates the distal tip being directed by pulling the wire 186. Although two wires are illustrated, one or more than two wires could be employed as would be apparent to one of skill in the art.

It should be understood that the foregoing description of the invention is intended merely to be illustrative thereof and that other equivalents, embodiments and modifications of the invention may be apparent to those skilled in the art.

CLAIMS

1. An instrument for creating a fluid jet, comprising:
a body including a lumen for conducting a high pressure fluid and at least one jet opening
at a distal tip of said body, in communication with said lumen, which forms a cutting jet as high
5 pressure fluid streams therethrough;
wherein said distal tip is selectively shapeable to vary the orientation of said at least one
jet opening.
2. The instrument recited in claim 1 wherein said selectively shapeable distal tip
10 includes a flexible distal tip and at least one control element having a first end connected to said
distal tip and a second end remote therefrom which is manipulable by a user to control the
orientation of said at least one jet opening.
3. The instrument recited in claim 2 wherein said at least one control element
15 includes a wire.
4. The instrument recited in claim 2, wherein said flexible distal tip further includes
a pleated portion on said distal end which is adapted to bend when subjected to a force
transmitted by said control element.
20
5. The instrument recited in claim 2 wherein said body includes at least one axially
extending lumen that supports said at least one control element.
6. The instrument recited in claim 1 wherein said at least one control element
25 includes a plurality of control elements diametrically spaced about said body.

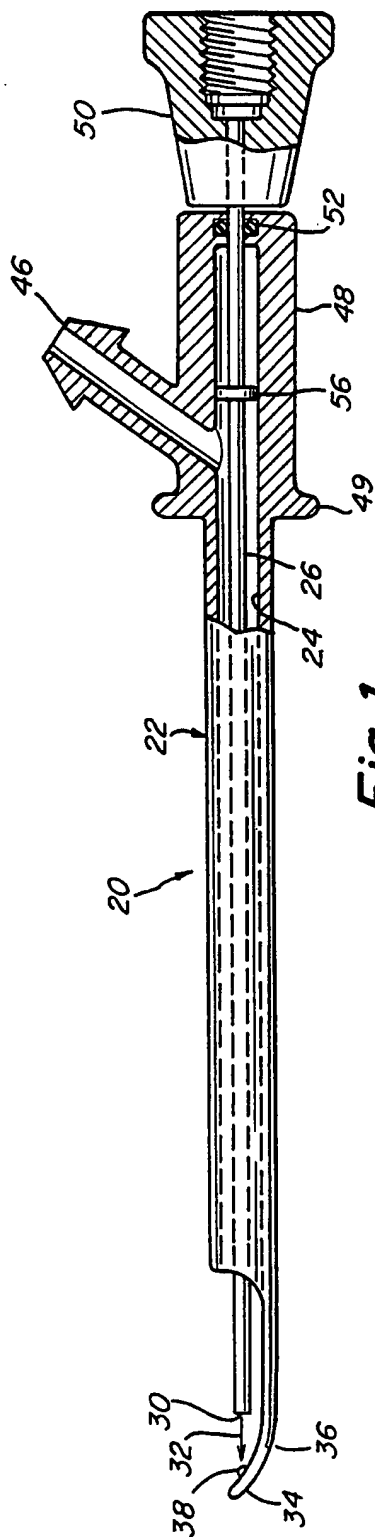


Fig. 1

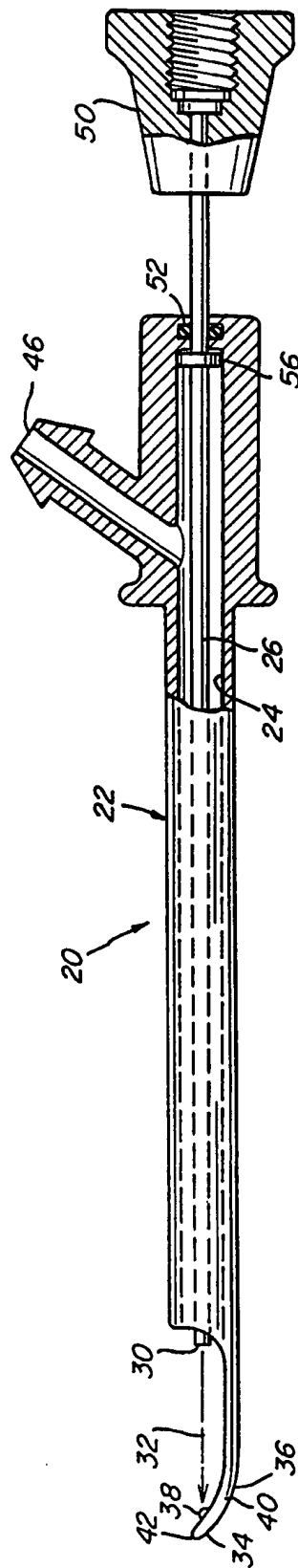
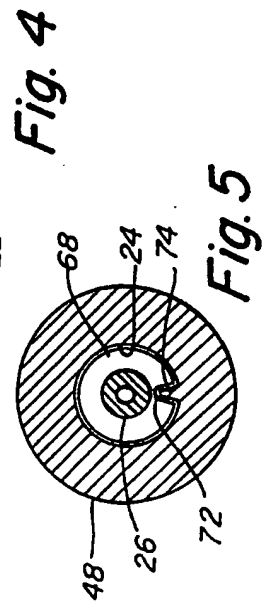
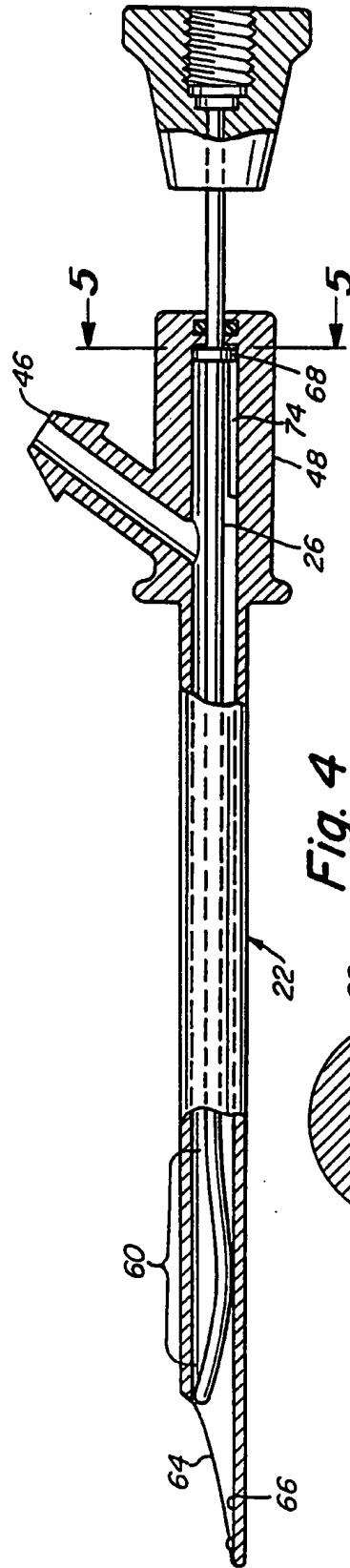
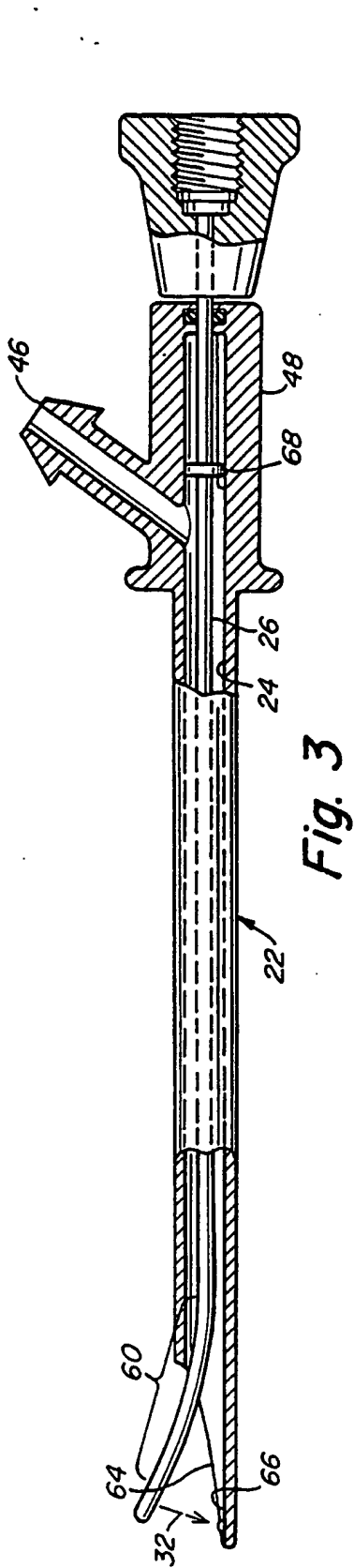


Fig. 2



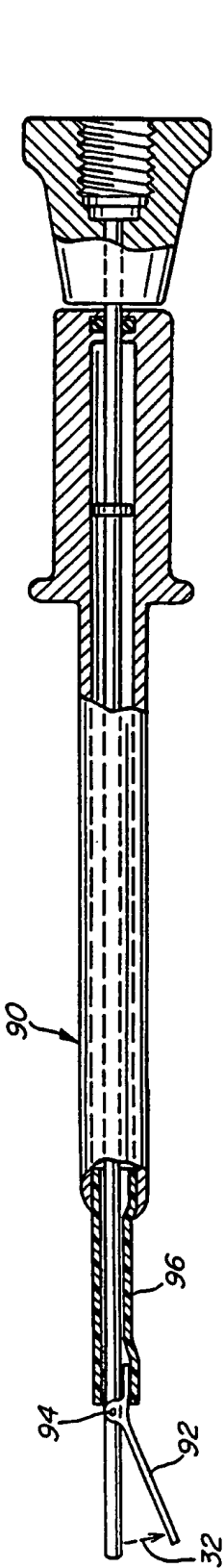


Fig. 6

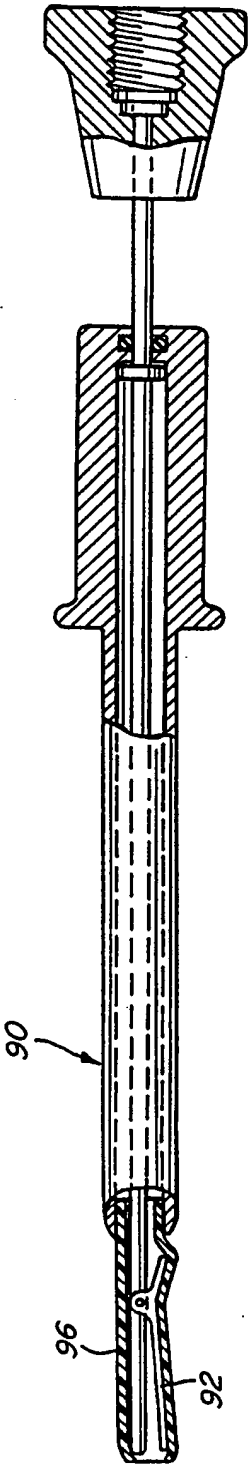
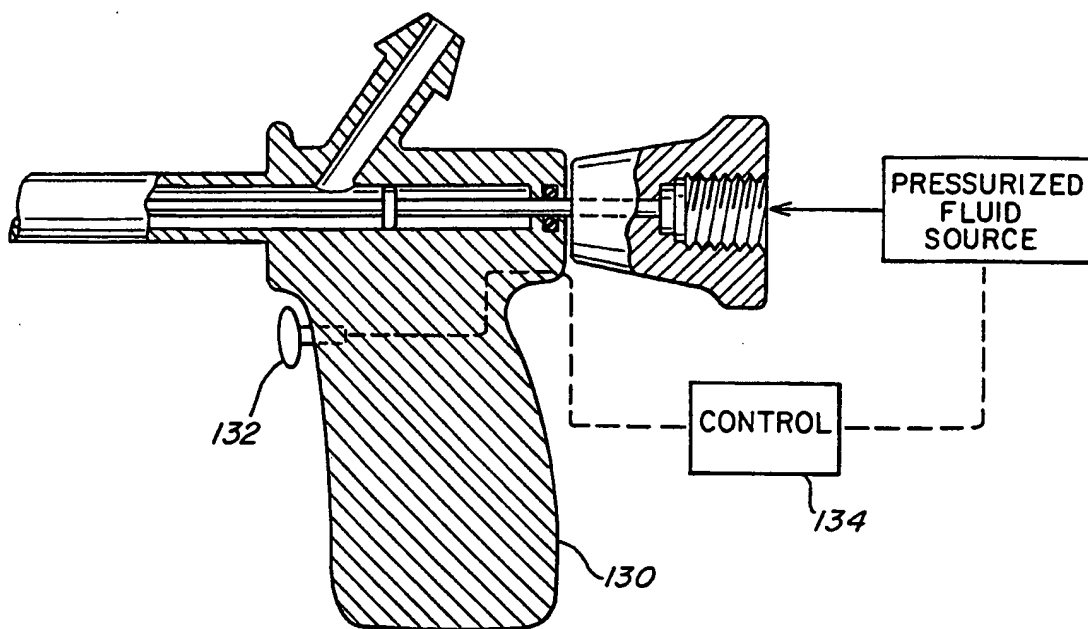
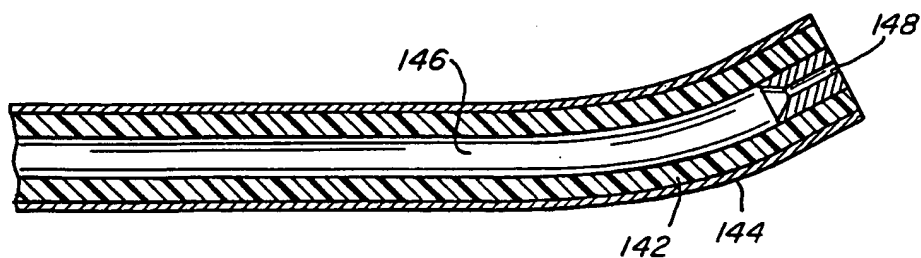
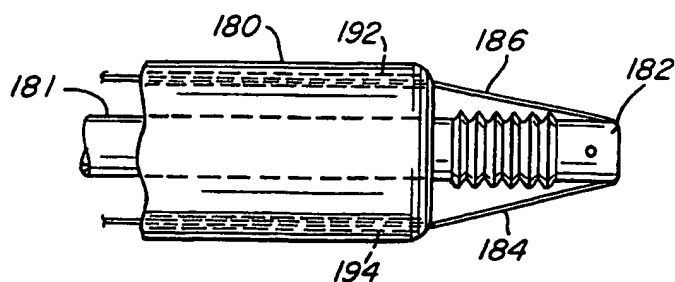
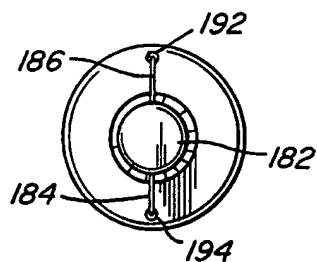
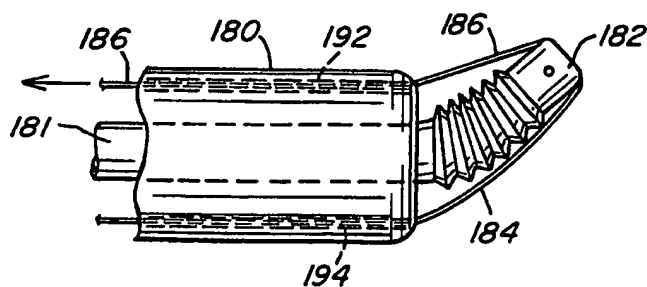


Fig. 7

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*Fig. 8**Fig. 9**Fig. 10*

5/5

*Fig. 11**Fig. 12**Fig. 13*

INTERNATIONAL SEARCH REPORT

 International application No.
 PCT/US96/09799
A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61B 17/22

US CL : 606/167

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/95; 606/1, 159, 167, 170

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 5,135,482 (NERACHER) 04 August 1992, see Fig. 1 and 14.	1 ----- 2-6
Y	US, A, 4,245,624 (KOMIYA) 20 January 1981, see Fig. 4, and column 4 lines 5-24.	2-6
Y	US, A, 4,403,985 (BORETOS) 13 September 1983, see Fig. 3, and column 1 lines 55-57	4

☐ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

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Date of the actual completion of the international search

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